

Experiment Number: 20727 - 02

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH  
AVERAGE SEVERITY GRADES[b]

Date Report Requested: 02/10/2012

Test Type: 90-DAY

ortho-Phthalaldehyde

Time Report Requested: 11:43:56

Route: RESPIRATORY EXPOSURE WHOLE BODY

CAS Number: 643-79-8

First Dose M/F: 01/19/09 / 01/19/09

Species/Strain: MICE/B6C3F1

Lab: BNW

F1\_M3

NTP Study Number: C20727

Lock Date: 08/21/2009

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

Study Gender: Both

TDMSE Version: 2.6.0.0\_007

PWG Approval Date: NONE

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First Dose M/F: 01/19/09 / 01/19/09

Lab: BNW

B6C3F1 MICE MALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
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**Disposition Summary**

Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Moribund Sacrifice					5	2
Natural Death						8
Survivors						
Terminal Sacrifice	10	10	10	10	5	
Animals Examined Microscopically	10	10	10	10	10	10

**ALIMENTARY SYSTEM**

Esophagus	(10)	(0)	(0)	(10)	(10)	(10)
Inflammation, Chronic Active						1 [2.0]
Necrosis						1 [3.0]
Gallbladder	(10)	(0)	(0)	(9)	(9)	(3)
Inflammation, Neutrophil	4 [1.0]					
Intestine Large, Cecum	(10)	(0)	(0)	(10)	(10)	(7)
Intestine Large, Colon	(10)	(0)	(0)	(10)	(10)	(8)
Intestine Large, Rectum	(10)	(0)	(0)	(10)	(10)	(7)
Intestine Small, Duodenum	(10)	(0)	(0)	(10)	(10)	(3)
Intestine Small, Ileum	(10)	(0)	(0)	(10)	(10)	(3)
Intestine Small, Jejunum	(10)	(0)	(0)	(10)	(10)	(3)
Liver	(10)	(0)	(0)	(10)	(10)	(10)
Necrosis					2 [1.0]	
Pancreas	(10)	(0)	(0)	(10)	(10)	(10)
Salivary Glands	(10)	(0)	(0)	(10)	(10)	(9)
Stomach, Forestomach	(10)	(0)	(0)	(10)	(10)	(9)
Hyperplasia, Squamous					1 [1.0]	
Stomach, Glandular	(10)	(0)	(0)	(10)	(10)	(8)

**CARDIOVASCULAR SYSTEM**

Blood Vessel	(10)	(0)	(0)	(10)	(0)	(2)
Heart	(10)	(0)	(0)	(10)	(10)	(10)

a - Number of animals examined microscopically at site and number of animals with lesion

b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

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Species/Strain: MICE/B6C3F1

Lab: BNW

B6C3F1 MICE MALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
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**ENDOCRINE SYSTEM**

Adrenal Cortex	(10)	(0)	(0)	(10)	(10)	(10)
Adrenal Medulla	(10)	(0)	(0)	(10)	(10)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(10)	(10)	(10)
Parathyroid Gland	(7)	(0)	(0)	(7)	(6)	(4)
Pituitary Gland	(10)	(0)	(0)	(9)	(10)	(9)
Thyroid Gland	(10)	(0)	(0)	(10)	(9)	(10)

**GENERAL BODY SYSTEM**

None

**GENITAL SYSTEM**

Epididymis	(10)	(0)	(0)	(10)	(10)	(10)
Preputial Gland	(10)	(0)	(0)	(10)	(10)	(10)
Inflammation, Chronic Active					1 [4.0]	
Prostate	(10)	(0)	(0)	(10)	(10)	(9)
Seminal Vesicle	(10)	(0)	(0)	(10)	(10)	(10)
Inflammation, Chronic					1 [2.0]	
Testes	(10)	(10)	(10)	(10)	(10)	(10)
Germinal Epithelium, Degeneration					2 [1.0]	

**HEMATOPOIETIC SYSTEM**

Bone Marrow	(10)	(0)	(0)	(10)	(10)	(10)
Hyperplasia				2 [1.0]	5 [1.4]	7 [1.9]
Lymph Node, Bronchial	(7)	(0)	(0)	(4)	(5)	(6)
Lymph Node, Mandibular	(4)	(0)	(0)	(6)	(9)	(5)
Lymph Node, Mediastinal	(4)	(0)	(0)	(1)	(4)	(3)
Lymph Node, Mesenteric	(10)	(0)	(0)	(10)	(10)	(7)

a - Number of animals examined microscopically at site and number of animals with lesion

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Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: MICE/B6C3F1

ortho-Phthalaldehyde

CAS Number: 643-79-8

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First Dose M/F: 01/19/09 / 01/19/09

Lab: BNW

B6C3F1 MICE MALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
Spleen	(10)	(0)	(0)	(10)	(10)	(10)
Atrophy, Lymphoid					10 [1.9]	
Thymus	(10)	(10)	(10)	(10)	(9)	(10)
Atrophy, Lymphoid					5 [1.4]	10 [2.7]
<b>INTEGUMENTARY SYSTEM</b>						
Skin	(10)	(10)	(10)	(9)	(10)	(10)
Hyperplasia, Squamous		1 [2.0]			9 [1.7]	4 [2.0]
Inflammation, Chronic Active				1 [1.0]	10 [1.8]	9 [1.1]
Ulcer					1 [1.0]	
Adnexa, Degeneration		2 [1.5]		4 [2.0]	1 [1.0]	6 [2.0]
Adnexa, Pinna, Degeneration						10 [2.0]
Epidermis, Necrosis						3 [2.0]
Epithelium, Hair Follicle, Parakeratosis		3 [1.0]	4 [1.0]	2 [1.0]	2 [1.5]	10 [1.8]
Epithelium, Hair Follicle, Pinna, Parakeratosis						10 [2.1]
Pinna, Hyperplasia, Squamous						10 [2.0]
Pinna, Inflammation, Chronic Active						10 [1.8]
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(10)	(10)	(10)
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(0)	(10)	(10)	(10)
<b>RESPIRATORY SYSTEM</b>						
Larynx	(10)	(10)	(9)	(10)	(10)	(10)
Inflammation, Chronic Active				4 [1.0]	10 [1.3]	10 [3.0]
Metaplasia, Squamous			1 [1.0]	10 [2.4]	10 [4.0]	8 [3.5]
Necrosis					1 [2.0]	10 [3.1]

a - Number of animals examined microscopically at site and number of animals with lesion

b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

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Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: MICE/B6C3F1

ortho-Phthalaldehyde

CAS Number: 643-79-8

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First Dose M/F: 01/19/09 / 01/19/09

Lab: BNW

B6C3F1 MICE MALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
Ulcer				1 [2.0]		
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Bronchiole, Goblet Cell, Hyperplasia				4 [1.0]		
Bronchus, Inflammation, Chronic Active				1 [2.0]		6 [1.5]
Bronchus, Metaplasia, Squamous				1 [2.0]		
Bronchus, Necrosis				2 [1.0]		9 [2.4]
Bronchus, Regeneration				1 [1.0]		1 [2.0]
Perivascular, Inflammation, Chronic Active				1 [1.0]		
Nose	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Suppurative		10 [2.1]	10 [2.7]	10 [4.0]	10 [3.2]	10 [1.9]
Glands, Olfactory Epithelium, Hyperplasia		11 [1.5]	10 [1.6]	7 [1.7]	6 [1.5]	
Glands, Respiratory Epithelium, Accumulation, Hyaline Droplet		7 [2.0]	10 [2.4]	6 [1.0]		
Olfactory Epithelium, Accumulation, Hyaline Droplet		10 [2.9]	10 [3.0]	10 [2.2]	9 [2.2]	
Olfactory Epithelium, Atrophy		10 [2.3]	10 [1.9]	10 [2.6]	10 [2.3]	10 [1.5]
Olfactory Epithelium, Metaplasia, Respiratory		1 [2.0]	8 [1.4]	10 [1.9]	4 [1.5]	
Olfactory Epithelium, Metaplasia, Squamous			2 [2.0]	1 [1.0]	2 [1.5]	
Olfactory Epithelium, Necrosis						5 [2.2]
Respiratory Epithelium, Accumulation, Hyaline Droplet		10 [3.0]	10 [3.5]	10 [3.8]	10 [2.0]	
Respiratory Epithelium, Metaplasia, Squamous		10 [1.7]	10 [2.1]	10 [2.7]	10 [2.4]	6 [1.2]
Respiratory Epithelium, Necrosis		2 [1.0]	6 [1.3]	5 [1.2]	9 [1.9]	10 [2.8]
Respiratory Epithelium, Regeneration			1 [1.0]		1 [2.0]	4 [1.3]
Respiratory Epithelium, Ulcer			3 [1.0]			
Turbinate, Atrophy		4 [1.0]	6 [1.7]	10 [2.8]	8 [2.4]	
Trachea	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active				1 [1.0]	9 [1.3]	10 [1.6]
Metaplasia, Squamous				3 [1.0]	10 [2.8]	3 [2.0]
Necrosis						9 [2.7]
Regeneration						5 [1.6]

**SPECIAL SENSES SYSTEM**

Eye	(10)	(10)	(10)	(10)	(10)	(10)
Cornea, Inflammation, Suppurative		1 [2.0]			1 [1.0]	4 [1.0]

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Test Type: 90-DAY

ortho-Phthalaldehyde

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Route: RESPIRATORY EXPOSURE WHOLE BODY

CAS Number: 643-79-8

First Dose M/F: 01/19/09 / 01/19/09

Species/Strain: MICE/B6C3F1

Lab: BNW

B6C3F1 MICE MALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
Cornea, Necrosis Harderian Gland	(10)	(0)	(0)	(10)	1 [1.0] (10)	(10)
<b>URINARY SYSTEM</b>						
Kidney Inflammation, Chronic Active	(10)	(0)	(0)	(10)	(10) 1 [4.0]	(10)
Nephropathy Urinary Bladder	2 [1.0] (10)	(0)	(0)	1 [1.0] (10)	1 [1.0] (10)	(10)

\*\*\* END OF MALE \*\*\*

a - Number of animals examined microscopically at site and number of animals with lesion

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Species/Strain: MICE/B6C3F1

Lab: BNW

B6C3F1 MICE FEMALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
<b>Disposition Summary</b>						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Moribund Sacrifice					4	1
Natural Death						9
Survivors						
Terminal Sacrifice	10	10	10	10	6	
Animals Examined Microscopically	10	10	10	10	10	10

**ALIMENTARY SYSTEM**

Esophagus	(10)	(0)	(0)	(0)	(10)	(10)
Gallbladder	(10)	(0)	(0)	(0)	(9)	(1)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(10)	(4)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(10)	(3)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(10)	(4)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(10)	(2)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(10)	(2)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(10)	(2)
Liver	(10)	(0)	(0)	(0)	(10)	(10)
Necrosis					1 [2.0]	
Pancreas	(10)	(0)	(0)	(0)	(10)	(8)
Cyst					1	
Salivary Glands	(10)	(0)	(0)	(0)	(10)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(10)	(7)
Stomach, Glandular	(10)	(0)	(0)	(0)	(10)	(7)

**CARDIOVASCULAR SYSTEM**

Blood Vessel	(10)	(0)	(0)	(0)	(9)	(0)
Heart	(10)	(0)	(0)	(0)	(10)	(10)

**ENDOCRINE SYSTEM**

a - Number of animals examined microscopically at site and number of animals with lesion

b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

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Species/Strain: MICE/B6C3F1

Lab: BNW

B6C3F1 MICE FEMALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
Adrenal Cortex	(10)	(0)	(0)	(1)	(10)	(10)
Adrenal Medulla	(10)	(0)	(0)	(1)	(10)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(10)	(8)
Parathyroid Gland	(6)	(0)	(0)	(0)	(5)	(4)
Pituitary Gland	(10)	(0)	(0)	(0)	(10)	(7)
Thyroid Gland	(10)	(0)	(0)	(0)	(10)	(10)

## GENERAL BODY SYSTEM

None

## GENITAL SYSTEM

Clitoral Gland	(9)	(0)	(0)	(0)	(8)	(8)
Ovary	(10)	(0)	(0)	(0)	(10)	(10)
Cyst	1 [2.0]					
Uterus	(10)	(0)	(0)	(0)	(10)	(8)

## HEMATOPOIETIC SYSTEM

Bone Marrow	(10)	(0)	(0)	(0)	(10)	(7)
Hyperplasia					8 [2.0]	
Lymph Node	(0)	(0)	(0)	(1)	(0)	(0)
Deep Cervical, Hyperplasia, Lymphoid				1 [2.0]		
Lymph Node, Bronchial	(4)	(0)	(0)	(0)	(6)	(7)
Lymph Node, Mandibular	(7)	(0)	(0)	(0)	(8)	(4)
Lymph Node, Mediastinal	(4)	(0)	(0)	(0)	(3)	(2)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(10)	(6)
Spleen	(10)	(0)	(0)	(0)	(10)	(8)
Atrophy, Lymphoid					1 [1.0]	8 [1.6]
Thymus	(10)	(10)	(9)	(10)	(10)	(10)
Atrophy, Lymphoid					6 [2.0]	10 [2.6]

a - Number of animals examined microscopically at site and number of animals with lesion

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ortho-Phthalaldehyde

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Lab: BNW

B6C3F1 MICE FEMALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(10)	(0)	(0)	(0)	(9)	(9)
Skin	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia, Squamous	3 [1.3]			6 [1.3]	9 [1.7]	6 [1.0]
Inflammation, Chronic Active	1 [1.0]	1 [1.0]	3 [1.0]	9 [1.1]	9 [1.9]	8 [1.3]
Adnexa, Degeneration	2 [1.0]			1 [1.0]		9 [1.3]
Adnexa, Pinna, Degeneration						10 [1.7]
Epidermis, Necrosis						5 [2.2]
Epithelium, Hair Follicle, Parakeratosis		3 [1.0]	7 [1.0]	9 [1.1]	10 [1.1]	10 [2.1]
Epithelium, Hair Follicle, Pinna, Parakeratosis						10 [2.0]
Pinna, Hyperplasia, Squamous						10 [1.5]
Pinna, Inflammation, Chronic Active						10 [1.4]
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(0)	(10)	(10)
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(0)	(0)	(10)	(10)
<b>RESPIRATORY SYSTEM</b>						
Larynx	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active					9 [1.9]	10 [3.1]
Metaplasia, Squamous			3 [1.3]	10 [2.1]	10 [3.9]	8 [3.8]
Necrosis					3 [2.0]	9 [2.6]
Regeneration						3 [1.7]
Ulcer						1 [2.0]
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Bronchiole, Goblet Cell, Hyperplasia					6 [1.5]	
Bronchus, Inflammation, Chronic Active					6 [1.2]	8 [1.4]
Bronchus, Necrosis					2 [2.0]	8 [2.8]

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Species/Strain: MICE/B6C3F1

ortho-Phthalaldehyde

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Lab: BNW

B6C3F1 MICE FEMALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
Bronchus, Regeneration						1 [1.0]
Bronchus, Ulcer						2 [2.5]
Nose	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Suppurative		10 [2.0]	10 [3.2]	10 [4.0]	10 [3.0]	6 [1.5]
Glands, Olfactory Epithelium, Hyperplasia		10 [2.1]	9 [2.1]	10 [1.5]	8 [2.0]	
Glands, Respiratory Epithelium, Accumulation, Hyaline Droplet		9 [2.1]	10 [2.1]	6 [2.0]	2 [1.0]	
Olfactory Epithelium, Accumulation, Hyaline Droplet		10 [3.0]	10 [2.8]	10 [2.0]	6 [1.3]	
Olfactory Epithelium, Atrophy		10 [2.3]	10 [2.1]	10 [2.6]	9 [2.4]	9 [1.8]
Olfactory Epithelium, Metaplasia, Respiratory		3 [1.3]	6 [1.2]	3 [1.0]	4 [2.3]	
Olfactory Epithelium, Necrosis		1 [1.0]			1 [2.0]	
Olfactory Epithelium, Regeneration					1 [2.0]	
Respiratory Epithelium, Accumulation, Hyaline Droplet		10 [3.0]	10 [3.3]	10 [3.6]	8 [2.0]	
Respiratory Epithelium, Metaplasia, Squamous		10 [2.0]	10 [2.7]	10 [2.7]	8 [2.6]	
Respiratory Epithelium, Necrosis		2 [1.0]	7 [1.1]	6 [1.3]	8 [1.5]	10 [2.5]
Respiratory Epithelium, Regeneration				1 [1.0]	3 [2.0]	6 [1.7]
Respiratory Epithelium, Ulcer						2 [1.0]
Turbinate, Atrophy		7 [1.0]	9 [2.1]	10 [3.3]	7 [3.1]	
Trachea	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active					10 [1.9]	10 [1.3]
Metaplasia, Squamous					9 [3.1]	2 [1.5]
Necrosis					2 [1.5]	10 [3.5]
Regeneration					1 [1.0]	2 [2.0]
Ulcer					1 [2.0]	

**SPECIAL SENSES SYSTEM**

Eye	(10)	(10)	(10)	(10)	(10)	(8)
Cornea, Inflammation, Suppurative					2 [1.0]	3 [1.0]
Cornea, Necrosis						2 [1.5]
Harderian Gland	(10)	(0)	(0)	(0)	(10)	(9)

a - Number of animals examined microscopically at site and number of animals with lesion

b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Experiment Number: 20727 - 02

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

Date Report Requested: 02/10/2012

Test Type: 90-DAY

ortho-Phthalaldehyde

Time Report Requested: 11:43:56

Route: RESPIRATORY EXPOSURE WHOLE BODY

CAS Number: 643-79-8

First Dose M/F: 01/19/09 / 01/19/09

Species/Strain: MICE/B6C3F1

Lab: BNW

B6C3F1 MICE FEMALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
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URINARY SYSTEM

Kidney	(10)	(0)	(0)	(0)	(10)	(10)
Nephropathy	1 [1.0]					
Urinary Bladder	(10)	(0)	(0)	(0)	(10)	(9)

\*\*\* END OF REPORT \*\*\*

a - Number of animals examined microscopically at site and number of animals with lesion

b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)